EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **MDL NO. 2187**

THIS DOCUMENT RELATES TO THE FOLLOWING INDIVIDUAL CASE:

EUNICE S. ARRUDA **Case No. 2:12-cv-8880**

RULE 26 EXPERT REPORT OF STEPHANIE MOLDEN, M.D., F.A.C.O.G., FPMRS

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All the opinions that I have offered in this report are given to a reasonable degree of medical probability and/or certainty, and they are based on my education, training, knowledge, experience and/or materials that I have reviewed in connection with this litigation. This report sets forth my opinions in the above-referenced case and bases therefor, but I understand my opinions related to these same issues will be more fully explored at my depositions. My *curriculum vitae*, which details my education and experience, and includes a list of all publications authored by me in the past 10 years, is attached to this report as **Exhibit A**. A list of the materials upon which I have relied is attached to this report as **Exhibit B**. I reserve the right to supplement this list, as well as the opinions expressed in this report.

My background and experience:

I am Dr. Stephanie Molden, board certified specialist in Female Pelvic Medicine & Reconstructive Surgery and Obstetrics & Gynecology. As previously noted, my CV is included as a summary of my training, including a formal three-year fellowship in Female Pelvic Medicine

& Reconstructive surgery, medical society memberships, as well as publications and research activities. I have published several articles in peer-reviewed journals, authored book chapters in several specialty related texts, and have served as course director in national surgical skill workshops in treatment of pelvic organ prolapse and urinary incontinence which have become my area of expertise.

I am presently the Medical Director of The Female Pelvic Health Center, LLC, in Newtown, Pennsylvania, which I opened in 2009.

During my three years of fellowship, I was trained heavily in mesh use for both prolapse and incontinence having assisted in and/or performed over 1000 cases in a high-volume teaching center. I performed and assisted in research involving mesh use and presented some of that research in both national and international arenas. I experienced both the before care and after care of many patients treated with mesh implants including caring for referred complications associated with such procedures. Since my training period, I have continued to incorporate mesh use in many procedures for urinary incontinence and pelvic organ prolapse adding to my experience and expertise and have now performed well over 2000 surgeries with a large percentage of those incorporating mesh slings and prolapse meshes of different types and brands. I also perform many traditional, non-mesh and robotic procedures depending on the patient and their individual findings. In addition to prolapse and incontinence, my practice consists largely of patients with pelvic pain, vulvodynia, and painful bladder syndrome disorders seeking treatment. Furthermore, I enjoy working on new product and procedure development for prolapse and incontinence to enhance and add to our current treatment options for women.

In addition to my medical practice, I serve as a research advisor for the Fellow's Pelvic Research Network (FPRN) sponsored by the Society for Gynecologic Surgeons where we assist

Fellows in female pelvic medicine and reconstructive surgery (FPMRS) and female urology on multicenter research projects. I serve as a reviewer for the Journal of Female Pelvic Medicine & Reconstructive Surgery. I am also a contributing member to the American Urogynecology Society's coding and reimbursement committee. I also take part in clinical research studies in my field.

In my current practice, I perform both mesh and non-mesh procedures for prolapse and incontinence and am taking part in the multicenter "522 studies" for current mesh prolapse repairs initiated at the request of the Food and Drug Administration (FDA). I offer both mesh and non-mesh repairs in my practice and feel that all options should be discussed and made available to our patients. I feel that it is my job as the physician to help guide my patients in their treatment decisions based on my clinical experience, the patient's needs and wishes, and interpretation of the medical evidence currently available.

Definition and background for SUI:

Stress urinary incontinence (SUI) is a highly prevalent condition noted by the loss of urine associated with increased bladder pressure such as during a cough, laugh, lifting or exercise and subsequent faulty closure of the urethra. SUI can result from weak muscles in the pelvic floor or a weak sphincter muscle at the neck of the bladder with risk factors for SUI including: obesity, smoking, chronic coughing, childbirth, diabetes, or an enlarged uterus such as due to fibroids. SUI is often a debilitating and bothersome condition that can substantially reduce a woman's quality of life; however, many women fail to report this condition to their doctors or seek treatment. Those women that do report it to their physicians typically wait many years from the onset of symptoms until they are desperate and symptoms are more severe. Although non-surgical treatments such as pelvic floor exercises and behavioral modification are helpful in alleviating symptoms in some

women, many need and proceed with surgery which is a more effective treatment for most (*Labrie et al NEJM 2013*).

The prevailing theory explaining stress urinary incontinence is that leakage from the urethra occurs when the intra-abdominal pressure exceeds the urethral pressure. Factors that affect the urethral pressure include bladder neck position, urethral sphincter muscle and nerve integrity, urethral smooth muscle and vascular plexuses, and surrounding tissue support. When the bladder fills with urine, the bladder wall accommodates this change in volume by expanding to keep the bladder pressure low. As filling increases, activation of a spinal sympathetic reflex inhibits detrusor muscle contraction to delay the need to void with concomitant activation of α-adrenergic receptors in the smooth muscle of the urethra increasing outlet resistance to prevent leakage. In addition, efferent pudendal nerve activity increases tone in the muscles of the pelvic diaphragm and striated urethral sphincter maintaining continence.

The vagina also provides a stable base on which the urethra and bladder neck rest. This stable suburethral layer of vaginal wall and endopelvic fascia prevents urethral and bladder neck descent, such that the urethra remains closed with straining. This is the "hammock" hypothesis of stress incontinence (*Delancey AJOG 1994*). Thus, a sling placed to treat stress incontinence would, following from the hammock hypothesis, be placed under the urethra with little or no tension, to provide a firm backdrop for the urethra to rest when intra-abdominal pressure increases to help maintain continence.

Surgical treatments for SUI:

Currently, the most common surgical treatment for SUI is the midurethral mesh sling based on the theory explained above. This can be placed in either a retropubic or transobturator placement. Traditionally, slings require a vaginal incision at the midurethral level as well as two

skin incisions either in the lower abdomen or groin region. Newer single incision mesh slings are placed through a single vaginal incision in a similar approach to an obturator sling but with no exit incisions and use of less mesh material leading to the possible benefit of fewer complications with similar success as we are now seeing in longer term studies.

Retropubic suspensions and anterior repairs, as well as colposuspensions including the Burch and Marshall-Marchetti-Krantz (MMK) procedures, were all popular non-mesh surgical options in the past but are much less commonly performed today. In 1997, the American Urological Association convened a clinical guidelines panel to analyze published outcomes data on surgical procedures to treat female SUI and to produce practice recommendations to guide surgical decision making (*Leach et al J Urol 1997*). They concluded that colposuspensions (e.g., Burch, MMK) and slings were more effective than transvaginal needle suspensions or anterior repairs for long-term success (48-month cure/dry rates). In 2004, Ward and Hilton demonstrated in a prospective randomized trial that the TVT sling was equal to or perhaps superior to the Burch colposuspension.

Further studies have compared mesh slings to non-mesh repairs demonstrating equal or greater efficacy and often lower complication rates such as Novara *et al.'s* systematic review and meta-analysis on colposuspensions, pubovaginal slings, and midurethral tapes (*Novara et al Eur Urol 2010*). With over 2000 studies in the literature reporting on mesh sling use for treatment of SUI, mesh slings have been shown to be effective objectively and subjectively in treating SUI with superior safety and efficacy (*Nilsson et al Int Urogynecol J 2013*).

In fact, no other procedure for SUI has been studied to the same degree. Fascial (autologous rectus fascia or allograft) slings have also been used with little long-term data, and the data that is available demonstrates a diminished success rate at 5 yrs. (*Brubaker et al J Urol 2012*)

with higher voiding dysfunction. The mesh midurethral sling is associated with less pain, shorter hospitalization, faster return to activities, and reduced costs as compared to previous options. Given this compelling data, the midurethral sling – either retropubic or transobturator – is now considered the "gold standard" in surgical treatment of SUI.

Risks/complications from the implantation of mesh to treat SUI:

Reported complications for mesh slings include:

- Erosion into viscera or extrusion through the vagina
- Voiding dysfunction or urinary retention
- Infection/inflammation
- Bleeding/hematoma formation
- Damage to blood vessels or nerves in surrounding tissue
- Pain or dyspareunia
- Bladder perforation
- Rarely, bowel perforation and death

The only unique risks to mesh sling surgical treatment for SUI versus other available surgical options for SUI are mesh erosion or extrusion. This mostly occurs in the vagina and is treatable with simple excision. Erosion into the bladder is less common. Erosion is not a unique complication to mesh only.

My experience with use of mesh in body:

I have utilized mesh in many patients with prolapse and incontinence for over thirteen years, beginning first in my residency and then throughout fellowship, and now in my own practice utilizing both abdominal and vaginal approaches. Overall, the majority of patients undergoing these procedures have done well with no recurrence or reoperation and with either no or few

complications. I have also taken care of my own and other surgeon's mesh complications. Furthermore, I have treated patients with non-mesh surgical failures as early as six weeks after primary repair with subsequent mesh repairs and with success. I have seen and treated non-mesh repairs for prolapse and incontinence with pain, dyspareunia, suture erosion, voiding dysfunction, and failures. Given that all surgical procedures have associated risks and complications, mesh procedures are no different but do offer certain advantages. I have rarely seen true infections related to proper mesh placement.

I have not seen convincing evidence that urinary tract infections occur more commonly after the initial postoperative period in mesh procedures and more frequently than prior to surgery and feel we must be careful in preoperative evaluation of urinary infections given the high rate of patients I see routinely who suffer from chronic cystitis often without awareness. Furthermore, many patients are treated with suggestive urinalysis testing only to find that the follow-up cultures are negative. I have personally experienced increased anatomical success rates and less reoperation for recurrence with mesh augmented repairs in general and feel that this a benefit of mesh as supported in the literature (*Hiltunen 2007 randomized trial, Nguyen 2008*).

It has become evident that correct placement and dissection techniques as well as patient selection are important to decrease the risks and complications associated with vaginal mesh surgery, as is the case with most surgical procedures. Furthermore, slings offer a minimally invasive, quick procedure from which most patients can undergo despite other medical conditions and recuperate well with excellent success rates as opposed to many of the procedures of the past.

Mesh tissue integration, pore size, normal wound healing process:

Polypropylene mesh has been used in most surgical specialties for over fifty years and has been placed in millions of patients. It is most commonly used in hernia repairs and has

permanently changed the techniques used daily in hernia surgery. The translation of its use in pelvic surgery was a natural one and based on the success and tolerability noticed in hernia repair.

Polypropylene is a thermoplastic polymer discovered in 1954 and used in a wide range of applications from common pill bottles and Rubbermaid containers for foods to the fine strands made into the sutures we have utilized in almost every surgery imaginable. This is due to its low cost, resilience and resistance to corrosion, strength, and inert properties. The long-term durability, safety, and efficacy of pelvic surgery to treat incontinence has been demonstrated for polypropylene sling use for up to seventeen years in studies (*Nilsson et al*).

Wound healing in the presence of polypropylene mesh is like that of usual tissue injury and healing including: hemostasis, inflammation, proliferation, and remodeling with scar formation. "There are seven interrelated and overlapping phases including: injury, protein absorption, acute inflammation, chronic inflammation, foreign body reaction (FBR), granulation tissue formation, and encapsulation. The host response to an implanted material is an unavoidable consequence associated with its use, and the end outcome of biomaterial implantation may depend upon local or systemic factors including site of implantation, quality of the tissue at the implantation site, and patient characteristics" (*Mohali et al 2014*).

Optimal mesh parameters include a mesh that is a knitted type 1 lightweight monofilament polypropylene material. It should be macroporous (>75 microns) to allow penetration by leukocytes and macrophages to prevent infection and to provide scaffolding for appropriate tissue in growth. Among the macroporous synthetic meshes, there is no consensus about a specific mesh design, in terms of pore size, knit design, etc., that produces the best clinical outcomes in SUI repairs with slings.

Description of Bard products at issue:

Align is Bard's suburethral mesh sling utilized for the treatment of stress urinary incontinence. It is available in transobturator, retropubic and suprapubic models. It consists of a polypropylene mesh tape delivered into the body with stainless steel introducers, or trocars leaving the mesh tape beneath the urethra in a tension free manner and buried beneath the full thickness vaginal epithelial layers.

Bard Instructions for Use (IFU):

I have reviewed the applicable Bard Instructions for Use (IFU) for the Align sling product. The IFU gives appropriate instructions on the use, delivery, contraindications and possible risks or complications associated with the Align device. It is easy to read and understand and supplies sufficient information such that an experienced pelvic surgeon would need in orderly to safely place the product. In my opinion, the IFU sufficiently addresses and explains the information the surgeon needs for safe and appropriate use of the Align device.

Bard training:

Training in use of mesh for treatment of SUI and prolapse is either obtained in residency/fellowship under direct supervision by an attending surgeon experienced in use of the products and/or by the medical device company's facilitation of physician educational events. This training may include didactic/cadaveric labs that are taught by expert physicians who use the products regularly. These sessions include two-way discussions between experienced surgeons and trainees on various issues including proper patient selection, operative techniques, pelvic anatomy, and prevention and care for complications.

In my experience, any surgeon considering use of a Bard product is offered expense-free attendance at these educational events to further their knowledge, experience and comfort before

use in patients. Furthermore, proctorships with an experienced surgeon present and often "scrubbed in" to assist the trainee surgeon are provided at no charge at the request of the trainee. It is up to the physician to determine their own comfort and need for such proctorship or the hospital department's credentialing process as to whether this is required. Further company support is provided continuously as desired by the surgeon, and contact with experienced surgeons to answer ongoing questions is facilitated. Providing training like Bard provided on the Align products is helpful to surgeons in advancing patient care and the Bard training provided appropriate information about product use, benefits, and risks.

FDA stance on transvaginal mesh:

To better understand the use of surgical mesh slings for SUI and evaluate their safety and effectiveness, the FDA held a panel meeting of scientific experts (Obstetrics and Gynecology Devices Panel of the Medical Device Advisory Committee) in September 2011 and conducted a systematic review of the published scientific literature from 1996 to 2011. For surgical mesh slings used for SUI, both the panel and the FDA's review found that:

- The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year. Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up.
- Mesh sling surgeries for SUI have been reported to be successful in approximately 70 to 80 percent of women at one year, based on women's reports and physical exams. Similar effectiveness outcomes are reported following non-mesh SUI surgeries.

- The use of mesh slings in transvaginal SUI repair introduces a risk not present in traditional non-mesh surgery for SUI repair, which is mesh erosion, also known as extrusion.
- Erosion of mesh slings through the vagina is the most commonly reported mesh-specific complication from SUI surgeries with mesh. The average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately two percent. Mesh erosion is sometimes treated successfully with vaginal cream or an office procedure where the exposed piece of mesh is cut. In some cases of mesh erosion, it may be necessary to return to the operating room to remove part or all the mesh.
- The long-term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA.
- The complications associated with the use of surgical mesh slings currently on the market for SUI repair are not linked to a single brand of mesh.

The FDA conducted a review of Medical Device Reports (MDRs) received from Jan. 1, 2008 through Sept. 30, 2011. During this time frame the FDA received 1,876 reports of complications associated with surgical mesh devices used to repair SUI. The most common complications reported through MDRs for surgical mesh slings for SUI repair, in descending order of frequency include: pain, mesh erosion through the vagina (also called exposure, extrusion or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuromuscular problems and vaginal scarring. Many of these complications require additional medical intervention, and sometimes require surgical

treatment and/or hospitalization. Apart from mesh erosion, the above complications can all occur following a non-mesh surgical repair for SUI as well, leaving mesh erosion or extrusion as the only unique complication with mesh use.

Through this review, the FDA fails to note the risks associated with *non-mesh treatments of SUI* which are often more severe such as bowel obstruction and perforation, wound dehiscence, greater infection risk, more voiding dysfunction, higher failure rates, longer hospital stays, and longer return to activities and work, not to mention higher costs. They also fail to note that long term studies are often not available on these alternative options that were often touted as "gold standards" prior to sling acceptance despite this lack of evidence that is now preached as necessary. The FDA further failed to note that mesh slings have more studies in the literature than any other procedure for incontinence and of a longer-term nature. Of note, the FDA panel of seventeen members that provided the update consists of only three out of twelve physician members that practice Urogynecology which may explain these discrepancies.

AUGS stance on slings:

AUGS published a supportive statement in January 2014 with respect to sling use for SUI ultimately stating that, "*The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.*"

Four key points were highlighted in this document including:

1. Polypropylene material is safe and effective as a surgical implant.
2. The monofilament polypropylene mesh midurethral sling is the most extensively studied anti-incontinence procedure in history.

3. Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.

4. The FDA has clearly stated that the polypropylene midurethral sling is safe and effective in the treatment of SUI.

AUGS and SUFU then issued another statement in 2016 in support of the use of the midurethral sling in the surgical management of stress urinary incontinence. It further states that "the safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year." This statement justified its position based on the following:

1. Polypropylene material is safe and effective as a surgical implant.
2. The monofilament polypropylene mesh midurethral sling is the most extensively studied anti-incontinence procedure in history.
3. Polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.
4. The FDA has clearly stated that the polypropylene midurethral sling is safe and effective in the treatment of SUI.

Furthermore, the 2016 statement concludes that this procedure is probably the most important advancement in the treatment of stress urinary incontinence for the last 50 years and has the full support of both organizations.

I agree with this position statement and feel it is a nonbiased statement based on the scientific evidence and was constructed by experienced specialists like myself who are looking out for the best interests of our patients.

MSDS:

I have reviewed the Marlex MSDS information for polypropylene cited by the Plaintiffs. However, this information would not be expected to be supplied or reviewed by surgeons regarding the materials used or implanted. This sheet does not address use of polypropylene in the form of grafts used in the human body and is aimed at identifying physical and chemical properties of the resin relating to processing, storage, handling and disposal. The hazards listed here are for those workers handling the chemical product and are not meant for or the same for patients in whom finished polypropylene products are used. If the MSDS is in question, then so is the use of all polypropylene whether it is in suture form or that used for containers containing foods we ingest. As a physician, I rely on the FDA standards to guide the decisions of safety for human use.

It is appropriate for the manufacturer of the finished product—like a surgical mesh made of polypropylene monofilaments that have been extruded, knitted, and sterilized, among other steps—to determine how the finished product can be used. The standards for what materials can be used in an implantable medical device come from the FDA, not from a raw material supplier or any entity that determines worker safety requirements. Nothing in the MSDS or related documents relating to arrangements for sourcing raw materials bears on the safety of the Align products, which are made of a well-accepted material.

Eunice Arruda Case

DOB 1/13/62

Complaints: pelvic pain, urinary retention, dyspareunia, decrease kidney function, anxiety/depression, UTI and kidney infections; using catheter and diapers daily

Implant: Align TO 12/4/08

PMHx:
Appendectomy 1968
Laminectomy 1979
Right shoulder acromioplasty 1980
Carpal tunnel release 1989
C-section due to placental abruption
Postpartum tubal ligation 3/2000
2002 menometrorrhagia – hysteroscopy, D&C
"kidney infection" 2002
Vaginal Hysterectomy, Ant repair/ Kelly urethral plication 5/30/2002, noted SUI
Postoperative urinary retention noted with foley and then catheter use until 7/16/02(PVR 550 on 6/10/02)
Pyelonephritis 8/12/02
Pelvic pain noted 2003, 2007, 2008 bilateral lower quadrant with bloating/distension- adhesions
Lap lysis of adhesions/BSO for chronic pelvic pain 3/6/2008
Sling 12/4/2008 for SUI with low urethral pressure
Sling revision 2/18/12
Prolapse diagnosed 3/2000
Diverticulitis (post)
Right renal stone (c/o abd pain2009)
GERD
COPD
Hyperlipidemia
Crohn's vs. Ulcerative colitis
Hypertension
Anxiety/Depression (pre)
?TIA/somatization 10/9/10
h/o tobacco use (1/2 ppd documented in 2000)
Fibromyalgia
early disability
Fatty liver/hepatomegaly
Shingles
Gastroparesis 2014
Overdose 2015 – Zoloft, Lexapro, Flomax, Ambien – "home stress with son"
Pneumonia
Neuropathy/radiculopathy
Lap diverting loop colostomy 7/11/16

Revision colostomy 11/18/16
2017 Bursitis rt hip – injections
7/14/17 Colostomy reversal and mesh abdominal defect

Notes:

Losing urine with standing – ISD?

4/2009 denies incontinence, +dyspareunia on Evista and Estrace, recurrent yeast

10/18/10 – new occ incontinence and frequency, weight gain 30 lbs

Pain again noted upper and lower right quadrant, prednisone for Crohn's

12/20/11 – c/o something "poking out" and vaginal dryness/irritation – normal exam Pfeiff

Pt c/o dryness, irritation, dyspareunia 1/2013 – normal U/A, atrophy noted-Vagifem Rx

2/13 – U/A normal, c/o discomfort, hip pain, Clobetasol Rx

3/2/13 – better on Clobetasol, pain iliac crest but normal xray

3/11/13 -PCP dx sacroiliitis

3/13- pyelo-E.Coli

4/1/13 – U/S no change in kidneys but high PVR 412cc

"no longer retaining urine" 5/7/13

Low back pain and radiation down rt leg noted 5/21/13; numbness tingling – MRI showed disc bulges L2-L5

Urogyn Dr. Gorman and Naim- slowed high capacity, inc emptying, hesitancy but good flow rate, neg LPPS, neg DO; MUCP 5, good flow rate at 25 ml/s, intermittent stream, mdet was 66 (slightly elevated) but normal at max flow; abnormal sphincter activity during voiding; they not postvoid bladder pressure and dyspareunia; urethral dilations performed 2013 and 2015

Pyelo again in 2013

2014 urecholine and bethanechol, Estrace

Sees Dr. Nikolavsky (urology) – normal cysto, Flomax trial

3/27/15 start PT; 5/22/15 "no complaint of pain currently"; incontinence of stool, burning feet

"suprapubic tenderness noted:

10/19/15Defecography 'paradoxical contraction of PR muscle w/inc evacuation– ant rectocele

Suprapubic burning despite self-cath and colostomy noted 10/24/16

11/20/17 notes use of diapers for fecal incontinence

Anal manometry 4/12/18 – c/w pelvic floor dysfunction

Ms. Arruda is currently a 58-year-old woman with many medical issues and generally appears very unhealthy for her age. She was 46 when she underwent the Align TO sling procedure for her stress urinary incontinence (SUI). Prior to that however, she also had Kelly plication of the urethra for SUI at the time of vaginal hysterectomy and anterior repair for a cystocele. After that original procedure she had trouble urinating and high residual urines. She again had this issue noticed after her sling procedure to the point that she needed to start self-catheterization. She did undergo removal of the mesh vaginally as much as possible for urinary retention/voiding dysfunction as well as pain in the obturator region which was thought to be due to her sling. Her pain did not seemingly improve but Ms. Arruda has a long history of back pain, hip pain, and upper and lower abdominal and pelvic pain that have been associated with DJD in her back, bursitis in her hip, as well as significant bowel issues and Crohn's disease. Her pain is so diffuse, and she has so many reasons for the pain that it is nearly impossible to attribute the pain to any one cause (including her sling and especially after removal). She had chronic pelvic pain specifically documented and even had a laparoscopic surgery due to this diagnosis prior to her sling placement with pain attributed at that time to adhesions and ovarian cysts. Furthermore, her suprapubic pain may be due to her incomplete bladder emptying or even interstitial cystitis (IC). IC was never entertained or treated and is more likely in patients with a history of depression and anxiety as well as stress, which she certainly had documented in dealing with her son and with attempt of overdose with medications. Furthermore, Ms. Arruda has evidence of pelvic floor dysfunction and paradoxical contraction of her puborectalis muscles on defecography. This is consistent with a high tone pelvic floor in general and associated pain as well as voiding dysfunction. Unfortunately, no direct examination findings were documented of

her other pelvic floor muscles directly, but it is likely that other muscles associated with the levator ani complex of musculature also display such findings and likely tenderness on examination, which may be part of her pelvic pain and dyspareunia complaints. Both IC and levator spasms/hypertonicity area associated with pain and dyspareunia and are not related to her sling. Obturator slings are usually the cause of direct obturator internus/externus and inner thigh adductor muscle pain syndromes as this is the area that the sling traverses during placement. Ms. Arruda also had documented dyspareunia prior to sling placement as well as fibromyalgia, which is a diffuse body pain condition and cannot be ruled out as a cause of her pelvic pain and dyspareunia as well.

With regard to Ms. Arruda's voiding dysfunction and urinary retention, she has a multifactorial etiology for this similar to her pain complaints. This was first documented after her first pelvic surgery (prior to her sling) and very well could have been initiated at that time since all incontinence procedures have urinary retention as a possible complication. She also has evidence of neuropathy in her lower extremities and even gastroparesis. She clearly is at risk for similar neuropathy of the bladder, or neurogenic bladder, which is unrelated to sling placement given these findings. This is especially likely given the nerve distribution of her examination findings and complains which are consistent with L2-L5 nerve roots and possibly sacral nerves as well which can certainly affect the bladder and pelvic floor muscles. It is very possible that Ms. Arruda has neuropathy affecting her bladder. Neuropathies can also cause urethral sphincter deficiency evidenced by her low urethral pressures on urodynamic testing (both before and after sling placement) which would explain her leakage with standing and position changes. It is also possible that Ms. Arruda had increased issues with voiding after her sling was placed and needed a revision much sooner than was done in this case. The success of sling revision for voiding

dysfunction decreases with prolonged time from placement as evidenced by the literature. Sling revision, especially with wide local removal such as was performed in her case, typically resolves sling associated urinary retention, especially when recognized early. In this case, her retention did not improve further implying another cause needs to be considered or that the revision was performed too late and further urethrolysis may have been warranted.

Ms. Arruda experienced many urinary infections and episodes of pyelonephritis. She did have documented UTIs prior to sling placement however, so this was not necessarily a new problem but perhaps worsened over time. This may have worsened due to several factors including: incomplete bladder emptying, self-catheterization, fecal incontinence, and atrophic genitourinary syndrome s/p menopause and elevated blood sugars noted on many occasions, as well as repeated steroid use for her joint pain and colitis episodes. This cannot be directly or solely related to sling placement given that all of these factors increase the risk of infection. Furthermore, Ms. Arruda is a long-term smoker which increases all risks and is likely related to many of her medical issues.

Following a differential diagnosis analysis and based upon my knowledge and experience as a Board Certified Female Pelvic Medicine and Reconstructive Surgeon and to a reasonable degree of medical probability and certainty, Ms. Arruda's complaints are not likely caused by the Bard Align product; no defect or action or inaction on the part of Bard caused or contributed to this patient's alleged injuries or damages. Moreover, use of a different available mesh product for her SUI procedure likely would not have avoided Ms. Arruda's complaints.

I reserve the right to modify this report as additional information is provided to me, including but not limited to additional medical records and the depositions of Plaintiff's experts,

which I understand will be scheduled in this matter. I also reserve my right to examination of the patient.

Dated: March 29, 2019

s/ Stephanie Molden
Stephanie Molden, M.D., F.A.C.O.G., FPMRS

Expert Testimony Given During the Previous Four Years

In Re: C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation,
Civil Action File No.:· 2:10-MD-2187.
Depositions provided on January 8 and 9, 2015 and July 19 and 20, 2017

Fee Schedule

-For case review, consultation, and conference calls: $750/hr in 15 min increments; for case reviews with less than 30 days notice a 50% increase in payment

-Deposition fees $5000 half day/$10,000 full day with minimum of a half day charge

-Court appearances $12,000 day

-For Travel time $400 hr in 30 minute increments outside the 4 (half day) and 8 (full day) time frame plus expenses.

-Full payment for cancellation/rescheduling within 2 weeks
50% payment for cancellation/rescheduling within 4 weeks

Dated: March 29, 2019

s/ Stephanie Molden
Stephanie Molden, M.D.,
F.A.C.O.G., FPMRS

Stephanie M. Molden, MD, FACOG, FPMRS

EDUCATION

Certificate in Biostatistics & Epidemiology - *Drexel University*, June 2009

Fellowship in Female Pelvic Medicine & Reconstructive Surgery (Urogynecology) – *St. Luke's Health Network & Institute for Female Pelvic Medicine,* Allentown/Bethlehem, PA (2006-2009)

Internship & Residency – *Abington Memorial Hospital,* Abington, PA (2002-2006)

M.D. - *University of Virginia*, Charlottesville, VA (1998-2002)

B.S. - *University of Virginia,* Charlottesville, VA (1994-1998)
Major - Biochemistry
Minor - Spanish
University of Valencia, Spain
UVA Study Abroad Program – Spanish instruction only
Fall semester, 1996

ACADEMIC APPOINTMENTS:

Clinical Instructor
St. Luke's Health Network
Department of Obstetrics & Gynecology
Bethlehem, PA
July 1, 2006 – June 24, 2009

Assistant Director of St. Luke's Center for Pelvic Health
701 Ostrum Street, Suite 108
Bethlehem, PA
July 1, 2008 - June 24, 2009

PROFESSIONAL EXPERIENCE

Medical Director/President
The Female Pelvic Health Center
& Surgicare Associates & Rejuvenation Medspa
760 Newtown-Yardley Rd, Suite 115
Newtown, PA 18940
July 2009 – present

Peer Reviews for Journal Publications:
Journal of Female Pelvic Medicine & Reconstructive Surgery
Journal of Women's Health

Medicolegal Consultant
Bard 2015-present

Medical Device Consultant/Instructor/Researcher
Ethicon: ~2008-2010
American Medical Systems (aka Astora): 2011-2016
Coloplast: 2016-present
Boston Scientific: 2017-present
Amphora: 2014-present
Thermiva: 2016-present

Speaker:
AMG pharmaceuticals- 2018

Fellow Physician
Department of Obstetrics & Gynecology: Division of Urogynecology
St. Luke's Hospital & Health Network &
The Institute for Female Pelvic Medicine & Reconstructive Surgery
Allentown/Bethlehem, PA 18104
July 2006 – June 2009

Administrative Chief Resident
Abington Memorial Hospital – Resident in Ob/Gyn (2002-2006)
1200 Old York Rd.
Abington, PA 19001

Medical Science Research Associate
Department of Hematology
University of Pennsylvania (Summer 1999)

Medical Science Research Associate
Department of Cell Biology
University of Virginia (Summer 1996)

BOARD EXAMINATIONS

FPMRS Subspecialty Board Examination: Passed on 1st attempt June 2013
ACOG Oral Board Examination: Passed on 1st attempt Dec 2011
ACOG Written Board Examination: Passed on 1st attempt June 2006

AWARDS and HONORS

Philadelphia Magazine Top Doctor 2017, 2018
Castle Connolly Top Doctors 2015, 2017, 2018
National Association Professional Women 2011-2012
Who's Who in Medicine and Healthcare 2011-2014
Cambridge Who's Who Executives 2009, 2011-2013
Philadelphia Area Reproductive Endocrine Society (PARES) 2nd place research award, 2005

Administrative Chief Resident (selected by Chairman), 2005-2006
Eleanor Widener Dixon research award - honorable mention, 2004
American Society for Hematology Research Scholarship, 1999
Lettie Pate Whitehead Scholarship, 2001 & 2002
Norfolk Foundation Scholarship, 2001
DAR Good Citizenship award, 1994
Lion's Club award 1994
Dean's List 1994, 1996, 1997

LEADERSHIP ROLES

Research Faculty Advisor
Fellows Pelvic Research Network (FPRN), Society of Gynecologic Surgeons (2009-present)
Ad Hoc Journal Research Reviewer
The Journal of Female Pelvic Medicine & Reconstructive Surgery (2011-present)
Medical Director/Chairperson
St. Mary Hospital Robotic Surgery Program (2011-2013)
Principal Investigator for Fellows Pelvic Research Network
Society for Gynecologic Surgeons (2008-2009)
Administrative Chief Resident – Ob/Gyn
Abington Memorial Hospital (Academic Year 2005-2006)
ACOG Junior Fellows Chairperson
Pennsylvania Section (2004-2005)
ACOG junior fellow representative lobby on congress 2005
ACOG Junior Fellows Vice-Chairperson
Pennsylvania Section (2003-2004)

COMMITTEE MEMBERSHIP

American Urogynecologic Society (AUGS) Coding & Reimbursement Committee
2016-present

Robotic Surgery Committee Chairperson
St Mary Medical Center 2011-2013

Fellows' Pelvic Research Network (FPRN) – Faculty Advisor
Society of Gynecologic Surgeons (2009-present)

Pelvic Trauma Taskforce
St. Luke's Hospital & Health Network (2008-2009)

Peer Investigational and Performance Review Committee (PIPR)
Abington Memorial Hospital, Dept of Ob/Gyn (2005-2006)

Failure Mode and Effect Analysis Committee (FMEA)
Abington Memorial Hospital, Dept of Ob/Gyn (2005-2006)

Medical School Electives Committee Student Representative
University of Virginia (2001)

MEDICAL LICENSURE
Pennsylvania – 2004- present
New Jersey – 2000- present
PROFESSIONAL SOCIETIES

American College of Obstetricians and Gynecologists (ACOG) - 2002-preent
Society for Gynecologic Surgeons – 2012-present (SGS – elected member)
American Urogynecology Society (AUGS) - 2006-present
Society for Urodynamics and Female Urology (SUFU) 2007- 2015
International Urogynecology Association (IUGA) - 2006-present
American Medical Association (AMA) – 2009-2012
National Association for Professional Women (NAPW) 2011-2013

LECTURES/PRESENTATIONS

Quality of Life, Sexual Health, and Anatomic Outcomes One Year after Transvaginal Mesh Reconstruction

- *Oral presentation, AUGS Scientific Meeting 2009*
  Hollywood, FL

Validated Measurements of Quality of Life and Sexual Function One Year After Transvaginal Mesh Reconstruction

- *Oral poster presentation, IUGA Scientific Meeting 2009*
  Lake Como, Italy

TVT Secur: One Year Outcomes

- *Poster presentation, IUGA Scientific Meeting 2009*
  Lake Como, Italy

Quality of Life Outcomes after Vaginal Reconstructive Surgery with Mesh

- *Oral presentation, SUFU Scientific Meeting 2009*
  Las Vegas, NV

"TVT Secur Surgical Technique and Learning Tips and Tricks", (video presentation).

- *Video presentation, IUGA Scientific Meeting 2008.*
  Taipai, Taiwan

"Surgical Revision of Midurethral Slings: Early versus Late Revision in Patients with Voiding Dysfunction"

- *Oral Presentation, SGS Scientific Meeting 2008*
  Savannah, GA

"Short Term Assessment of Patients Undergoing the New Tension Free Vaginal Tape Secur Procedure for Treatment of Stress Urinary Incontinence"

- *Oral Poster Presentation, IUGA Scientific Meeting 2007*
  Cancun, Mexico

"Multicenter Short-Term Assessment of Patients Undergoing the New Tension Free Vaginal Tape Secur Procedure for Treatment of Stress Urinary Incontinence"

- *Poster Presentation, AUGS Scientific Meeting 2007*
  Palm Springs, CA

Resident Lecture Series (2006-2008):

"Basic Evaluation of the Urogynecology Patient"
"Pelvic Anatomy I & II"
"Prolapse and the POPQ Exam"
"Basics of Urodynamics"
"Surgical Treatment of Stress Urinary Incontinence"
"Surgical Pitfalls & Complications"
"TVT-Secur: The New Frontier"
"Vaginal Masses, Lumps, & Bumps"
"Urinary Tract Infections"
"Interstitial Cystitis"
"Fecal Incontinence"
"Pessaries"
"Laparoscopic tips" & lab

"Seasonality of spontaneous and IVF pregnancy, and temperature and humidity effect on IVF"

- *Poster Presentation, ASRM October 2004*
  Philadelphia, PA
- *Annual Research Day Presentation*
  Abington Memorial Hospital, May 2006

"Chlamydia Antibody Testing and Tubal Factor Infertility"

- *Department of Reproductive Endocrinology & Infertility, UNC Chapel Hill*
  May 2005

"Ovarian Hyperthecosis" case presentation and discussion

- *Annual Abington Memorial Hospital Education Day*
  September 2004

"Congenital Diaphragmatic Hernia"

- *Perinatal & Neonatal Conference, Abington Memorial Hospital*
  October 2003

"Timing of Neonatal Injury/Asphyxia"

- *Perinatal & Neonatal Conference, Abington Memorial Hospital*
  January 2004

PUBLICATIONS

Ehsani N. …. **Molden SM**. Risk Factors for Synthetic Mesh Extrusion Following Abdominal Sacral Colpopexy and Vaginal Mesh Procedures. *Female Pelvic Med Reconstr Surg.* 2012 Nov-Dec;18(6):357-61.

Harvie H, **Molden S**, et al. IRB Variability in Multicenter Urogynecology Studies. *Female Pelvic Med Reconstr Surg.* 2012 Mar-Apr;18(2):89-92.

Molden SM. Addressing the silent suffering. *Ostomy Wound Manag*. 2011 Dec;57(12):2.

Molden S, Patterson D, Tarr M, Sanses T, Bracken J, Nguyen A, Harvie HS, White A, Hammil SA, Murphy M, Rogers RG. Risk factors leading to midurethral sling revision: a multicenter case-control study. *Int Urogynecol J*. Oct;21(10):1253-9.

Molden S, Bracken J, Nguyen A, Harvie HS, Whit A, Hammil SL, Patterson D, Tarr M, Sanses T, Murphy M, Rogers RG. A Retrospective Multicenter Study on Outcomes after Midurethral Polypropylene Sling (MUS) Revision for Voiding Dysfunction. *J Female Pelvic Med & Reconstr Surg*. 2010 Nov;16(6):340-4.

Sanses T, Shahryarinejad A, **Molden S**, et al. Anatomic Outcomes of Vaginal Mesh Procedure Compared to Uterosacral Ligament Suspension and Abdominal Sacrocolpopexy for Pelvic Organ Prolapse. *Am J Obstet Gynecol* Aug 2009 Nov;201(5): 519.e1-8. doi: 10.1016/j.ajog.2009.07.004. Epub 2009 Aug 28.

van Raalte H, Lucente VR, **Molden S**, Haff R, Murphy M. One-year Anatomic and Quality of Life Outcomes Following the Prolift Procedure for Treatment of Posthysterectomy Prolapse. *Am J Obstet Gynecol*. 2008 Dec;199(6):694.

Murphy M, Sternschuss G, Haff R, van Raalte H, **Saltz S**, Lucente VR. Quality of life and surgical satisfaction following vaginal reconstructive versus obliterative surgery for the treatment of advanced pelvic organ prolapse. *Am J Obstet Gynecol.* 2008 May;198(5):573.

Murphy M, Shrestha R, Haff R, van Raalte H, **Molden S**, Lucente V. Vaginal Hysterectomy at the Time of Transvaginal Mesh Placement in the Treatment of Utero-vaginal Prolapse. *J Fem Pelvic Med & Reconstr Surg.* 2010 Sep;16(5):272-7.

Molden S, Lucente VR. "New Minimally Invasive Slings: TVT-Secur**"** *Current Urology Reports.* 2008 Sep;9(5):358-61

Lucente V, **Molden S,** S. Barker, M. Karram. "Current Debate: Transvaginal Placement of Synthetic Grafts for the Repair of Pelvic Organ Prolapse (Pro)" *Current Urology Reports* 2008.

Molden, S, **Lucente, V**, *et al*, *Suburethral Sling Procedures,* Glob. *libr. women's med*., *(ISSN: 1756-2228)* 2008; DOI 10.3843/GLOWM.10068.

Saltz S. Amenorrhea. Chapter in: Obstetrics and Gynecology: Pearls of Wisdom. 2005.

Saltz S. Endometriosis and Adenomyosis. Chapter in: Obstetrics and Gynecology: Pearls of Wisdom. 2005.

ABSTRACTS

Ehsani N, **Molden S,** et al. Risk Factors for Synthetic Mesh Extrusion Following Abdominal Sacral Colpopexy and Vaginal Mesh Procedures. 2012

Molden S, Lucente V, Haff R, van Raalte H, Murphy M. Quality of Life, Sexual Health, and Anatomic Outcomes One Year after Transvaginal Mesh Reconstruction.

Rhee S, Lucente V, van Raalte H, **Molden S**, Murphy M. Long-Term Quality of life and Anatomic Outcomes with Total Vaginal Mesh Reconstruction for the Post-Hysterectomy Patients. American Urogynecology Society. Hollywood, FL 2009.

Molden S, Lucente V, van Raalte H, Haff R**,** Murphy M. Validated Measurements of QOL and Sexual Function in Women One Year After Transvaginal Mesh Reconstruction. International Urogynecology Association. Lake Como, Italy. June 2009.

Molden S, van Raalte H, Haff R, Lucente V. TVT Secur: One Year Outcomes. International Urogynecology Association. Lake Como, Italy. June 2009.

Lucente V, van Raalte H, Haff R**, Molden S,** Ehsani N, Murphy M. Validation of a New Post-Surgical Quality of Life Tool: The Surgical Satisfaction Questionnaire (SS-8). International Urogynecology Association. Lake Como, Italy. June 2009.

Ehsani N, Murphy M, van Raalte H, **Molden S**, Haff R, Lucente, V. Four Month and One Year Results of Transvaginal Mesh Placement (Prolift) in the Treatment of Pelvic Organ Prolapse. International Urogynecology Association. Lake Como, Italy. June 2009.

Molden S, Lucente V, van Raalte H, Lipetskaia L, Haff R**,** Murphy M. Validated Measurements of QOL and Sexual Function in Women Undergoing Transvaginal Mesh Reconstruction. Society for Urodynamics & Female Urology. Las Vegas, NV. Feb 2009.

Lucente V, Haff R, **Molden S**. "TVT Secur Surgical Technique and Learning Tips and Tricks", (video). International Urogynecology Association Scientific Meeting. Taipai, Taiwan. Sept 2008.

van Raalte H, Murphy M, **Molden S**, Rogerson E, Haff R, Lucente V. Anatomic and Functional Outcomes of a New Rectocele Repair Technique Incorporating the Transvaginal Plication of the Rectal Muscularis Layer. International Urogynecology Association Scientific Meeting. Taipai, Taiwan, Sept 2008.

Molden SM, Lucente VR, van Raalte H, Lipetskaia L, Haff R, Murphy M. Surgical Revision of Midurethral Slings: Early versus Late Revision in Patients with Voiding Dysfunction. Annual Scientific Meeting of the Society of Gynecologic Surgeons. Savannah, GA, April 2008.

Saltz S, Haff R, Lucente VR. Short Term Assessment of Patients Undergoing the New Tension Free Vaginal Tape Secur Procedure for Treatment of Stress Urinary Incontinence**.** International Urogynecologic Association in Cancun, Mexico, June 2007.

Saltz S, Miklos J, Moore R, Haff R, Lucente VR. Multicenter Short-Term Assessment of Patients Undergoing the New Tension Free Vaginal Tape Secur Procedure for Treatment of Stress Urinary Incontinence. Annual Scientific Meeting of the American Urogynecologic Society in Hollywood, FL September 2007.

Murphy M, Sternschuss G, Haff R, van Raalte H, **Saltz S**, Lucente VR. Quality of Life and Surgical Satisfaction following Vaginal Reconstructive versus Obliterative Surgery for the Treatment of Advanced Pelvic Organ Prolapse. Annual Scientific Meeting of the American Urogynecologic Society in Hollywood, FL September 2007 and International Continence Society in Rotterdam, Netherlands, August 2007.

Saltz S, Schinfeld J, Somkuti S, Barmat L. Seasonality of spontaneous pregnancy and IVF, and the effect of temperature and humidity on IVF. Annual Scientific Meeting of the American Society of Reproductive Medicine, Philadelphia, PA; October 2004

Saltz S, Schinfeld J, Somkuti S, Barmat L. Reduction in IVF multiple gestations from 1999 to 2004 in response to ASRM recommendations on number of embryos transferred.

CURRENT RESEARCH

- Restorelle Transvaginal Mesh versus Native Tissue Repair for Treatment of Pelvic Organ Prolapse, Restorelle 522 Study, SU014
- Aquinox 1125-301 The LEADERSHIP 301 Trial: A 12-Week, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Phase 3 Trial to Evaluate the Efficacy and Safety of 2 Doses of AQX-1125 Targeting the SHIP1 Pathway in Subjects with Interstitial Cystitis/Bladder Pain Syndrome Followed by an Extension Period
- Emsella chair treatment for urinary incontinence
- The Neuguide System for Vaginal Colpopexy of Uterine Prolapse Post-arketing Surveillance Clinical Study

Exhibit B

Arruda, Eunice
List of Materials Considered for Dr. Stephanie M. Molden

Legal Documents
Arruda Short Form Complaint
Depositions
Eunice Arruda 3-12-19 (rough draft)
Defendants' Fact Sheets
Arrud, Eunice - MDL Bard Defense Fact Sheet
BARD_DFS_ARRUDA_EUNICE_000001
BARD_DFS_ARRUDA_EUNICE_000029
BARD_DFS_ARRUDA_EUNICE_000031
BARD_DFS_ARRUDA_EUNICE_000032
BARD_DFS_ARRUDA_EUNICE_000033
BARD_DFS_ARRUDA_EUNICE_000034
BARD_DFS_ARRUDA_EUNICE_000057
Verification
Expert Reports
190222.Arruda.OstergardRep.Final.Executed
190222.ExpertDisclosures
Plaintiff Fact Sheets
705618_002_001_ArrudaEuniceS_PlaintiffFactSheet_00000001_00000025
Medical Records
Arruda Eunice - Chronology - 03.07.19
705618_003_001_ArrudaEuniceS_PlaintiffSuppliedRecs_00000001_00000186
705618_008_001_ArrudaEuniceS_OneidaHealthcareCtrRadDept_00000001_00000004
705618_035_001_ArrudaEuniceS_WomensHealthAssocsofOneida_00000001_00000001
705618_035_002_ArrudaEuniceS_WomensHealthAssocsofOneida_00000002_00000204
705618_059_001_ArrudaEuniceS_UpstateUnivHospPathDept_00000001_00000001
705618_063_001_ArrudaEuniceS_UnivOBGYNAssocsMedRecsDept_00000001_00000001
705618_067_001_ArrudaEuniceS_StJosephsHospHealthCtrRadDept_00000001_00000001
Arruda.081204.Implant
Arruda.081204.Sticker Page
Arruda.120216.Op Report.Excise
ArrudaEuniceS_MorrisvilleFamilyPhysicians_00000001_00000517

ArrudaEuniceS_StJosephsHospHealthCtrMedRecsDept_00000001_00000229
ArrudaEuniceS_StJosephsHospHealthCtrPathDept_00000001_00000001
ArrudaEuniceS_StJoseph_sMedPC_00000001_00000014
ArrudaEuniceS_UpstateUnivHospMedRecsDept_00000001_00000750
ArrudaEuniceS_UpstateUnivHospMedRecsDept_00000751_00001493
ArrudaEuniceS_UpstateUnivHospPatientAccts_00000001_00000007
ArrudaEuniceS_UpstateUnivHospRadDept_00000001_00000001

DESCRIPTION	DATE	BATES (IF APPLICABLE)
1 - Align Urethral Support System Instructions for Use		
PK0301736 (English Portion Only) Urethral Support System	No date	AVA20246236 - AVA20246240
PK0301796 (English Portion Only) One page Addendum to be used with Align Urethral Support System and Align TO Trans-Obturator Urethral Support System.	09/05/07	AVA20034375 - AVA20034376
PK0301941 (English Portion Only) Urethral Support System	02/00/2008	AVA2E7416807 - AVA2E7416812
PK0302350 (English Portion Only) Urethral Support System	04/00/2010	AVA2E0083767 - AVA2E0083772
PK0302260 (English Portion Only) Urethral Support System	10/00/2009	AVA20246407 - AVA20246412
PK0301735 (English Portion Only) Trans-Obturator Urethral Support System	No date	AVA20246232 - AVA20246235
PK0301796 (English Portion Only) One page Addendum to be used with Align Urethral Support System and Align TO Trans-Obturator Urethral Support System.	03/00/2007	AVA20034375 - AVA20034376
PK0301942 (English Portion Only) Trans-Obturator Urethral Support System	02/00/08	AVA20246650 - AVA20246656
PK0302349 (English Portion Only) Trans-Obturator Urethral Support System	4/00/10	AVA2E7220413 - AVA2E7220418
PK0302261 (English Portion Only) Trans-Obturator Urethral Support System	10/00/09	AVA2E8659583 - AVA2E8659588
2 - Various Align Transvaginal Mesh Literature		
A cohort study comparing a single-incision sling with retropubic midurethral sling, by Madsen, El-Nashar, Woelk, Klingele, Gebhart, Trabuco	08/06/13	N/A
A Real-World Comparative Assessment of Complications Following Various Mid-Urethral Sling Procedures for the Treatment of Stress Urinary Incontinence, by Magee, Roy, Hinoul, Moretz, Kozarev, Waters, Whitmore	00/00/2012	N/A
Abdel-Fattah M, Ramsay I, Pringle S. Lower Urinary Tract Injuries After Transobturator Tape Insertion By Different Routes: A Large Retrospective Study. BJOG 113:1377–1381.	00/00/00	N/A
Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG, et al. Incidence and management of graft	00/00/11	N/A
Afonso, Rmn Jorge, Ps Martinis, Ms Soldi, Ol Alves, B Patricio, T Mascarenhas, Mgf Sartori, Mjbc Girao. Structural And Thermal Properties Of Polypropylene Mesh Used In Treatment Of Stress Urinary Incontinence. Acta of Bioengineering and Biomechanics Vol. 11, No 3.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Albo ME, et al,. . Burch colposuspension versus fascial sling to reduce urinary stress incontinence. NEJM 356(21) p 2143-55.	00/00/00	N/A
Alfonso, PALS Martins, MJBC Girao, RM Natal Jorge, AJM Ferreira, T Mascarenhas, AA Fernandes, J Bernardes, EC Baracat, G Rodrigues De Lima, B Patricio. Mechanical Properties Of Polypropylene Mesh Used In Pelvic Floor Repair. Int Urogynecol J 19:375-380.	00/00/00	N/A
Amaro, Joao; Hamilto Yamamoto, Paulo Kawano, Guilherme Barros. Clinical And Quality-Of-Life Outcomes After Autologous Fascial Sling And Tension-Free Vaginal Tape: A Prospective Randomized Trial.	00/00/00	N/A
Amrute, Kaytan V. The Science Behind Biomaterials In Female Stress Urinary Incontinence Surgery.	00/00/00	N/A
Analytical, Occupational and Toxicologic Aspects, by Frostling, Hoff, Jacobsson, Pfaffli, Vainiotalo, Zitting	00/00/84	N/A
Anger J. T. , et al. ,. Trends in surgical management of stress urinary incontinence among female Medicare beneficiaries. Urology 74(2), p. 283-287.	00/00/00	N/A
Appell, et al. Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update, American Urological Association.	00/00/09	N/A
Arco F. , et al. TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress	00/00/00	N/A
Ariane Cortesse, Bernard Jacquetin, Philippe Grise, Loïc Le Normand, François Richard and François Haab.	2007	
Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: are additional intraoperative sterility procedures useful?, by Vollebregt, Troelstra, Vaart	09/02/09	N/A
Bafghi, Abdolreza. Multifilament Polypropylene Mesh For Urinary Incontinence 10 Cases Of Infections Requiring Removal Of Sling.	00/00/00	N/A
Bai, Sang Wook. Treatment Outcome Of Tension-Free Vaginal Tape In Stress Urinary Incontinence: Comparison Of Intrinsic Sphincter Deficiency And Nonintrinsic Sphincter Deficiency Patients.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Barber, MD, Kleeman S, Karram MK, Et Al. Transobturator Tape Compared With Tension-Free Vaginal Tape For The Treatment Of Stress Urinary Incontinence: A Randomized Controlled Trial. Obstet Gynecol 111:611-21.	00/00/00	N/A
Barry, Christopher. A Multi-Centre Randomized Clinical Control Trial Comparing The Retropubic Rp Approach Versus The Transobturator Approach To For Tension-Free Suburethral Sling Treatment Of Urodynamic Stress Incontinence The Torp Study.	00/00/00	N/A
Boyles, S. ; Edwards, R. Complications Associated With Transobturator Sling Procedures.	00/00/00	N/A
Brent A. Parnell, Md; Elizabeth A. Johnson, Np, Phd; And Denniz A. Zolnoun, Md, Mph. Genitofemoral And Perineal Neuralgia After Transobturator Midurethral Sling.	00/00/00	N/A
Chapple, Christopher R. ; Haab, Francois; Cervigni, Mauro; Dannecker, Christian; Fianu-Jonasson, Aino; Sultan, Abdul H. An Open, Multicentre Study Of Nasha/Dx Gel (Zuidex) For The Treatment Of Stress Urinary Incontinence.	00/00/00	N/A
Chen, H. ; Ho, M. Analysis Of Risk Factors Associated With Vaginal Erosion After Synthetic Sling Procedures For Stress Urinary Incontinence.	00/00/00	N/A
Choe, Jong M. Autologous Cadaveric And Synthetic Materials Used In Sling Surgery Comparative Biomechnical Analysis.	00/00/00	N/A
Choe, Jong M. The Use Of Synthetic Materials In Pubovaginal Sling.	00/00/00	N/A
Clemons, et al. Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members' Use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery. Female Pelvic Medicine & Reconstructive Surgery, Volume 19, Number 4, July/August 2013.	08/00/13	N/A
Comparing the Risk of Urethrolysis for the treatment of voiding dysfunction between two retropubic mesh slings: a case-control study, by Kawasaki, Edenfield, Visco, Wu, Westreich, Siddiqui	08/22/12	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Comparison of Outcomes Between Different Sub-Urethral Sling Procedures for Female Stress Urinary Incontinence: Analysis from a Hospital Database, by Magee, Subramanian, Moretz, Kozarev, Waters, Hinoul	05/16/11	N/A
Cortesse, Arianne; Bernard Jacquetin, Philippe Grise, Loïc Le Normand, François Richard And François Haab. Prospective Multicenter Clinical Trial Of Uretex Sup For Surgical Treatment Of Stress Urinary Incontinence. International Journal of Urology14, 611–615 .	00/00/00	N/A
Cox, A., S. Herschorn, and L. Lee, Surgical management of female SUI: is there a gold standard? Nat Rev Urol, 2013. 10(2): p. 78-89.	00/00/13	N/A
Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was know, by Ostergard	04/22/11	N/A
Enzelsberger H, Schaluphy J, Heider R, Mayer G. TVT Versus TOT-A Prospective Randomized Study For The Treatment Of Female Stress Urinary Incontinence At A Follow-Up Of 1 Year. Geburtshilfe Frauenheilkd 65:506–511.	00/00/00	N/A
Evans, Doug. Design Summary Natural Tissue Self-Anchoring Sling With Versatile Introducer.	00/00/00	N/A
Falconer, C. Influence Of Different Sling Materials On Connective Tissue Metabolism In Stress Urinary Incontinent Women.	00/00/00	N/A
Fitzgerald, J. Mollenhauer, And L. Brubaker. Failure Of Allograft Suburethral Slings.	00/00/00	N/A
Funk, et al. Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors. American Journal of Obstetrics & Gynecology. January 2013.	01/00/13	N/A
Gebhart & Deborah A. Dixon & Emanuel C. Trabuco & Christopher J. Klingele & Stephanie M. Bagniewski & Amy L. Weaver. Three-Year Outcomes Of Uretex Urethral Support System For Treatment Of Stress Urinary Incontinence. Int Urogynecol J 19:1075–1079.	00/00/00	N/A
Gomelsky, Alex; Dmochowski, Roger R. Biocompatability Assessment Of Synthetic Sling Materials For Female Stress Urinary Incontinence.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Harvard Publications; Midurethral Sling Surgery For Stress Incontinence.	00/00/00	N/A
Hilger, Wesley S. ; Jeffrey L. Cornella. Rectovaginal Fistula After Posterior Intravaginal Slingplasty And Polypropylene Mesh Augmented Rectocele Repair.	00/00/00	N/A
Hinoul P, et al. A randomized controlled trial comparing an innovative single incision sling with an established Transobturator sling to treat female stress urinary incontinence. Journal of Urology 185(4) p 1356-1362.	00/00/00	N/A
Hinoul, Piet. Surgical Management Of Urinary Stress Incontinence In Women A Historical And Clinical Overview.	00/00/00	N/A
John B. Gebhart & Deborah A. Dixon & Emanuel C. Trabuco & Christopher J. Klingele & Stephanie M. Bagniewski & Amy L. Weaver. Three-Year Outcomes of Uretex Urethral Support System For Treatment Of Stress Urinary Incontinence. Int Urogynecol J 19:1075–1079.	2008	
JS Afonso, PALS Martins, MJBC Girao, RM Natal Jorge, AJM Ferreira, T Mascarenhas, AA Fernandes, J Bernardes, EC Baracat, G Rodrigues De Lima, B Patricio. Mechanical Properties of Polypropylene Mesh Used In Pelvic Floor Repair. Int Urogynecol J. 19:375-380.	2008	
Kawasaki A, Edenfield Al, Visco Ag, Wu Jm, Westreich D, Siddiqui Ny. Comparing The Risk Of Urethrolysis For The Treatment Of Voiding Dysfunction Between Two Retropubic Mesh Slings: A Case-Control Study. Int Urogynecol J. Apr;24(4):589-94.	00/00/00	N/A
Kim Y-W, Na Y-G, Sul C-K. Randomized Prospective Study Between Pubovaginal Sling Using Sparc Sling System And Monarc Sling System For The Treatment Of Female Stress Urinary Incontinence: Short Term Results. Korean J Urol 46:1078–1082.	00/00/00	N/A
Kobashi, Kathleen. Erosion Of Woven Polyester Pubovaginal Sling.	00/00/00	N/A
Kuuva, N. , Nilsson, C. G. A Nationwide Analysis Of Complications Associated With The Tension-Free Vaginal Tape (Tvt) Procedure.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Lapitan M. C. M, et al,. Open retropubic colposuspension for urinary incontinence in women. Cochrane Database of Systematic Reviews.	00/00/00	N/A
Latthe Pm, Foon R, Toozs-Hobson P. Transobturator And Retopubic Tape Procedures In Stress Urinary Incontinence: A Systematic Review And Meta-Analysis Of Effectiveness And Complications. BJOG 114:522-31 Erratum, BJOG114:1311.	00/00/00	N/A
Leach GE, Dmochowski RR, Appell RA Et Al. Female stress Urinary Incontinence Clinical Guidelines Panel. Summary Report On Surgical Management Of Female Stress Urinary Incontinence. J Urol 158:875–880.	00/00/00	N/A
Letters to the Editor of Jornal of Urology RePost-Implantation Alterations of Polypropylene in the Human and Author Reply	05/00/13	N/A
Liapis, A. Monarc Vs TVT-O For The Treatment Of Primary Stress Incontinence A Randomized Study.	00/00/00	N/A
Long-Term Outcomes After Robotic Sacrocolpopexy in Pelvic Organ Prolapse: Prospective Analysis, by Sierra, Oshiro, Perez, Fomo, Rosillo, Nogal, Vela, Moyano, Fernandez-Represa	02/24/11	N/A
Lucente, V. Adjust Single Incision Transobturator Sling Procedure For Stress Urinary Incontinence In Women One Year Results.	00/00/00	N/A
Luck, Ali M. Short-Term Efficacy And Complications Of Posterior Intravaginal Slingplasty.	00/00/00	N/A
Meschia M, Pifarotti P, Bernasconi F, Et Al. Multi Center Randomized Trial Of TVT And IVS For The Treatment Of Stress Urinary Incontinence In Women. International Continence Society. Abstract 385.	00/00/00	N/A
Meschia, Michele. Short-Term Outcomes With The Ajust System A New Single Incision Sling For The Treatment Of Stress Urinary Incontinence.	00/00/00	N/A
Mesh Contraction - Myth or Reality, by Dietz, Erdmann, Shek	02/00/11	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Moalli & Noah Papas & Shawn Menefee & Mike Albo & Leslie Meyn & Steven D. Abramowitch. Tensile Properties Of Five Commonly Used Mid-Urethral Slings Relative To The TVT. Int Urogynecol J 19:655–663.	00/00/00	N/A
Moalli, Pamela A., Brown, Bryan, Reitman, Maureen. Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J. DOI 10.107/s00192-014-2343-8; January 2014.	01/00/14	N/A
Morey, Allen F. Transobturator Versus Transabdominal Mid Urethral Slings A Multi-Institutional Comparison Of Obstructive Voiding Complications.	00/00/00	N/A
Morley R. and Nethercliffe J. Minimally invasive surgical techniques for stress incontinence surgery. Best Pract ResClin Obstet Gynaecol 19(6): p. 925-40.	00/00/00	N/A
Mostafa, Alyaa, Wael Agur, Mohamed Abdel-All, Karen Guerrero, Chu Lim, Mohamed Allam, Mohamed Yousef, James N'Dow, And Mohamed Abdel-Fattah. Multicenter Prospective Randomized Study Of Single-Incision Mini-Sling Vs Tension-Free Vaginal Tape-Obturator In Management Of Female Stress Urinary Incontinence: A Minimum Of 1-Year Follow-Up. Urology 82 (3), p 552-559.	00/00/00	N/A
Nager, Charles W. A Randomized Trial Of Urodynamic Testing Before Stress-Incontinence Surgery.	00/00/00	N/A
Naumann G, Hagemeier T, Zachmann S, Al-Ani A, Skala C, Albrich S, Koelbl H. Ajust Fully Adjustable Single Incision Sling For The Treatment Of Stress Urinary Incontinence : 1 Year Follow-Up On A New Minimal-Invasive Treatment For Female Sui.	00/00/00	N/A
Neuman, M. Posterior Intra-Vaginal Slingplasty For The Treatment Of Vaginal Apex Prolapse Medium-Term Results Of 140 Operations With A Novel Procedure.	00/00/00	N/A
Nilsson, C. ; Palva, K. Eleven Years Prospective Follow-Up Of The Tension-Free Vaginal Tape Procedure For Treatment Of Stress Urinary Incontinence.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Novara G, Galfano A, Boscolo-Berto R Et Al. Complication Rates Of Tension-Free Midurethral Slings In The Treatment Of Female Stress Urinary Incontinence: A Systematic Review And Meta-Analysis Of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes To Other Surgical Procedures And Different Devices. Eur Urol 53:288–309.	00/00/00	N/A
Novara, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W. Tension-Free Midurethral Slings In The Treatment Of Female Stress Urinary Incontinence: A Systematic Review And Meta-Analysis Of Randomized Controlled Trials Of Effectiveness. Eur Urol 52:663-78 Erratum, Eur Eurol 52:1548.	00/00/00	N/A
Ogah J. , et al. ,. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews.	00/00/00	N/A
Ogah, J. ; Cody, D. Minimally Invasive Synthetic Suburethral Sling Operations For Stress Urinary Incontinence In Women: A Short Version Cochrane Review. Neurology and Urodynamics. 30: 284-291, 2011.	00/00/11	N/A
Ostergard, Donald R. and Azadi, Ali. To mesh or not to mesh with polypropylene: does carcinogenesis in animals matter? Int Urogynecol J. DOI 10.1007/s001192-013-2239-z; September 20, 2014.	09/20/14	N/A
Otcenasek M, Halaska M, Krcmar M, Maresova D, Halaska Mg. New Approach To The Urogynecological Ultrasound Examination. Eur J Obstet Gynecol Reprod Biol. Jun 10;103(1):72-4.	06/00/10	N/A
Paparella R, Marturano M, Pelino L, Scarpa A, Scambia G, La Torre G, Paparella P. Prospective Randomized Trial Comparing Synthetic Vs Biological Out-In Transobturator Tape: A Mean 3-Year Follow Up Study. Int Urogynecol J 21:1327–1336.	00/00/00	N/A
Pariente, J. An Independent Biomechanical Evaluation Of Commercially Available Suburethral Slings.	00/00/00	N/A
Petros, P. ; Richardson, P. Midurethral Tissue Fixation System Sling - A 'Micromethod' For Cure Of Stress Incontinence - Preliminary Report.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Petros, P. ; Richardson, P. Tissue Fixation System Posterior Sling For Repair Of Uterine/Vault Prolapse - A Preliminary Report.	00/00/00	N/A
Polypropylene as a Reinforcement in Pelvice Surgery is Not Inert: comparative analysis of 100 explants, by Arnaud Clave, Yahi, Hammou, Montanari, Gounon, Henri Clave	01/06/10	N/A
Polypropylene mesh and the host response, by Patel, Ostergard, Sternschuss	03/20/12	N/A
Polypropylene Mesh: Evidence for Lack of Carcinogenicity, by Moalli, Brown, Reitman, Nager	03/11/14	N/A
Randomized Trial of Graft Materials in transbturator tape operation: biological versus synthetic, by Ururlucan, Erkan, Onal, Yalcin	11/27/12	N/A
Rechberger T, Furyma K, Jankiewicz K, Adamiak A, Skorupski P. The Clinical Effectiveness Of Retropubic (Ivs-02) And Transobturator (Ivs-04) Midurethral Slings: Randomized Trial. Eur Urol 56:24-30.	00/00/00	N/A
Richter, Ph. D. , M. D. , Michael E. Albo, M. D. , Halina M. Zyczynski, M. D. ,Kimberly Kenton, M. D. , . Retropubic versus Transobturator Midurethral Slings for Stress Incontinence. NEJM VOL 362 NO 22.	00/00/00	N/A
Roth, Ted M. Management Of Persistent Groin Pain After Transobturator Slings.	00/00/00	N/A
Schneider, Mary Ellen; Miller, Charles E. Fda Warns Of Risk With Transvaginal Mesh; Treating Advanced Pelvic Prolapse; Midurethral Sling Surgery For Stress Incontinence; Fpags Pelvic Anatomy And Gynecology Surgery Symposium: The Premier Dilemmas In Minimally Invasive Gynecologic Surgery. Harvard Health Publications.	00/00/00	N/A
Schraffordtkoops, Steven. What Determines A Successful Tension-Free Vaginal Tape? A Prospective Multicenter Cohort Study Results From The Netherlands Tvt Database.	00/00/00	N/A
Slack, M. In Vivo Comparison Of Suburethral Sling Materials.	00/00/00	N/A
Starkman, Jonathan S. Vesicovaginal Fistula Following A Transobturator Midurethral Sling Procedure.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Stephen M, Coomes B, Barrington J – Torbay Hospital. The Align Urethral Support System For The Surgical Management Of Stress Urinary Incontinence In Women. ICS Scientific Programme Poster 837.	00/00/00	N/A
Surgical Treatmment of Stress Urinary Incontinence: a 3-Year Follow-Up, by Bandiera, Giunta, Aloisi, Arena, Iozza, Matarazzo, Morello, Raciti, Rapisarda, Vitale, Cianci	00/00/2008	N/A
Tcherniakovsky, Cesar Fernandes, Carlos Bezerra, Carlos Del Roy, Eric Wroclawski. Comparative Results Of Two Techniques To Treat Stress Urinary Incontinence: Synthetic Transobturator And Aponeurotic Slings.	00/00/00	N/A
Téllez Martínez-Fornés M, Fernández Pérez C, Fouz López C, Fernández Lucas C, Borrego Hernando J. ;. A Three-Year Follow-Up Of A Prospective Open Randomised Trial To Compare Tension-Free Vaginal Tape With Burch Colposuspension For Treatment Of Female Stress Urinary Incontinence.	00/00/00	N/A
The align urethral support system for the surgical management of stress urinary incontinence in women, by Stephen, Coomes, Barrington	00/00/09	N/A
Tilemachos Kavvadias, Daniel Kaemmer, Uwe Klinge, Stefanie Kuschel, And Bernhard Schuessler. Foreign Body Reaction In Vaginally Eroded And Noneroded Polypropylene Suburethral Slings In The Female: A Case Series.	00/00/00	N/A
To Mesh or Not to Mesh with Polypropylene: does carcinogenesis in animals matter, by Ostergard, Azadi	03/11/14	N/A
Togami, Joanna M;Krlin, Ryan;Dmochowski, Roger R;Winters, J Christian. Biomaterials In The Treatment Of Pelvic Organ Prolapse And Stress Urinary Incontinence An Update.	00/00/00	N/A
Tommaselli GA, et al,. Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow up. International Urogynecoloy J 21 p 1211-1217.	00/00/00	N/A
Ugurlucan Fg, Erkan Ha, Onal M, Yalcin O. Randomized Trial Of Graft Materials In Transobturator Tape Operation: Biological Versus Synthetic. Int Urogynecol J. Aug;24(8):1315-23.	00/00/00	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Ulmsten, U. ; Petros, P. Intravaginal Slingplasty (Ivs): An Ambulatory Surgical Procedure For Treatment Of Female Urinary Incontinence.	00/00/00	N/A
Usefulness of retropubic tape for recurrent stress incontinence after transobturator tape failure, by Sabadell, Poza, Esgueva, Moreles, Sanchez-Iglesias, Xercavins	07/06/11	N/A
Vandevord PJ, Broadrick Km, Krishnamurthy B, Singla AJ. A Comparative Study Evaluating The In Vivo Incorporation Of Biological Sling Materials. Urology 75:1228–1233.	2010	
Vandevord Pj, Broadrick Km, Krishnamurthy B, Singla Aj. A Comparative Study Evaluating The In Vivo Incorporation Of Biological Sling Materials. Urology 75:1228–1233.	00/00/00	N/A
Walsh CA. TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months. British Journal of Urology Int.	00/00/00	N/A
Wang Ac, Lin Yh, Tseng Lh, Chih Sy, Lee Cj. Prospective Randomized Comparison Of Transobturator Suburethral Sling (Monarc) Vs. Suprapubic Arc (Sparc) Sling Procedures For Female Urodynamic Stress Incontinence. Int Urogynecol J 17:439–443.	00/00/00	N/A
Ward Kl, Hilton Pa. A Prospective Multicenter Randomized Trial Of Tension-Free Vaginal Tape And Colposuspension For Primary Urodynamic Stress Incontinence: Two-Year Follow-Up. Am J Obstet Gynecol 190:324-31.	00/00/00	N/A
Ward Kl, Hilton Pa. Prospective Multicenter Randomized Trial Of Tension-Free Vaginal Tape And Colposuspension For Primary Treatment For Stress Incontinence. BMJ 325:67-70.	00/00/00	N/A
Weinberger, Michael E; Donald Ostergard. Long-Term Clinical And Urodynamic Evaluation Of The Polytetrafluoroethylene Suburethral Sling For Treatment Of Genuine Stress Incontinence.	00/00/00	N/A
3 - AUGS-SUFU		
AUGS Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	01/03/14	N/A
AUGS FAQS by Patients Mid-Urethral Slings for Stress Urinary Incontinence	No date	N/A
AUGS FAQS by Providers Mid-Urethral Slings for Stress Urinary Incontinence	No date	N/A

DESCRIPTION	DATE	BATES (IF APPLICABLE)
4 - Various Corporate Documents and Testimony		
Aviles, Alejandro - Dep Transcript*	10/17/14	N/A
Bracken, Ronald - Dep Transcript*	06/24/14	N/A
Brown, JaMarr - Dep Transcript*	09/11/14	N/A
Darois, Roger - Dep Transcript*	06/19/13	N/A
Freitag, Walter - Dep Transcript*	08/17/14	N/A
Hennick, Mike - Dep Transcript*	10/02/14	N/A
Smith, Bradley - Dep Transcript*	09/17/14	N/A
Zakrzewski, Frank (Revised) - Dep Transcript*	03/07/14	N/A
Bobby Orr Memorandum (DX 0256)	09/02/08	AVA2E0087163 - AVA2E0087167
TSM 308: Chemical Resistance of Marlex® Polypropylene Memorandum	00/00/00	CP-00091 - CP-00094
MSDS - Marlex Polypropylene	02/28/01	CP-00035 - CP-00041
MSDS - Marlex Polypropylene	02/13/08	AVA2E1281085 - AVA2E1281093
WEB Study Lightweight Mesh Design: Preclinical Evaluation in a Rabbit Model (DX 0623)	05/08/09	AVA2E0726028 - AVA2E0726050
Davol StudyBard Soft Mesh Animal Study Report (DX 0300)	11/12/07	AVA2E1974644 - AVA2E1974906
Al Jacks Spreadsheet Reporting on Surgical Mesh Complications	12/00/08	AVA20503356-AVA20503360
Sling Integration Team - Project 4663; Summary Feedback from Sling Integration Cadaver Labs and Surgeon Feedback	10/26/06	AVA20111301-AVA20111305
Customer Preference Evaluation and Design Validation Summary Report: align Urethral Support System & Align TO Trans-Obturator Urethral Support System; Revision 0		AVA2E6653324-AVA2E6653327
Design Qualification and 510(k) Testing for Bard Sling Mesh (SA300052)		AVA2E3484570-AVA2E3484583
Design Qualification and Competitive Product Testing for Bard Sling Mesh (SA0300052); Revision 1; Interim Report	01/22/07	AVA2E0398398-AVA2E0398413
Subject Product Analysis and Health Hazard Evaluation for CAPA	07/09/02	AVA20545558-AVA20545754
5 - 510(k) Submissions Pertaining to Align		
K070073 - Align 510(k)	01/05/07	AVA20155659 - AVA20155931
K093747 - Align 510(k)	12/02/09	AVA20162160 - AVA20162416
6 - FDA Exec Sum on Surgical Mesh for Trx of Women with PO Prolapse and SU Incontinence		
Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence Urogyn Mesh Panel Meeting FDA Executive Summary	09/08/11	N/A
7 - MDU Training Materials		

DESCRIPTION	DATE	BATES (IF APPLICABLE)
Bard MDU Clinical Education Continuum	No date	AVA2E1730369 - AVA2E1730382
8 - Trial Transcript (s)		
Cisson v. C. R. Bard, Inc.	Various	N/A
9 - Miscellaneous		
All Materials cited or referenced in my Expert Report	Various	Various